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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/633,697	08/05/2003	Pablo Umana	1975.0010005/TJS/AWL	5455

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EXAMINER	
GUZO, DAVID	

ART UNIT	PAPER NUMBER
1636	

MAIL DATE	DELIVERY MODE
09/10/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/633,697	UMANA ET AL.	
	Examiner	Art Unit	
	David Guzo	1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 August 2006 and 21 May 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *86-123,125-149 and 151-165* is/are pending in the application.

4a) Of the above claim(s) *133-149,151-157,161 and 162* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *See Continuation Sheet* is/are rejected.

7)☒ Claim(s) *89, 92-96, 99-101, 104-105, 108-109, 114-119, 122, 126-128, 130 and 158* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *8/21/06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Continuation of Disposition of Claims: Claims rejected are 86-88,90,91,97,98,102,103,106,107,110-113,120,121,123-125,129,131,132,159,160 and 163-165.

Detailed Action

Claims 133-149, 151-157 and 161-162 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 12/30/05.

Priority for claims 90, 94, 96, 97, 101, 106-108, 114, 127 and 128 is granted back to the filing date of the instant application (8/5/2003) as support for the claimed invention is not found in parent applications 09/294,584 and 60/082,581. Priority for the remaining claims is granted back to the filing date of the 60/082,581 application (4/20/98).

Applicants argue that the instant claims are supported by the disclosures of the parent applications. The arguments presented by applicants appear to be contained in the traverse of the outstanding 35 USC 112, 1st paragraph rejections (Enablement and Written Description). The examiner's response to said arguments will be presented in the response to applicants' traverse of the 35 USC 112, 1st paragraph (New Matter) rejection.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 90, 94 and 101 stand rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

This rejection is maintained for reasons of record in the previous Office Action (Mailed 4/11/06) and for reasons outlined below. However, applicants' arguments regarding support for claims directed to modifying the activity of the three enzymes GnT III, α-mannosidase II and β(1,4)-N-acetylglucosaminyltransferase as well as a method for producing a recombinant antibody having increased ADCC wherein said antibody has an increased proportion of nonfucosylated oligosaccharides or wherein the predominant N-linked oligosaccharide is nonfucosylated or wherein the predominant N-linked oligosaccharide in the Fc region is not a high-mannose structure are persuasive.

Applicants traverse this rejection by asserting that, with regard to support for "a method for producing a recombinant antibody having increased ADCC comprising altering (i.e. decreasing) the activity of core α-1,6- fucosyltransferase or modifying the activity of the three enzymes GnTIII, a-mannosidase II and β(1,4)-N-acetylglucosaminyltransferase.", the specification (page 38, lines 2-6) teaches that GnTIII blocks the activity of the core α-1,6- fucosyltransferase and hence there is support for claims reciting altering the activity of this enzyme.

Applicant's arguments filed 8/21/06 have been fully considered but they are not persuasive. The instant claims recite a method comprising use of a host cell which

"[h]as an altered level of activity of" core α-1,6- fucosyltransferase. The term "altered level of activity" reads on increasing or decreasing the activity of the enzyme in the cell, by, for example, altering the amount of the enzyme in the cell or modifying the enzyme molecule itself to increase/decrease the activity of the enzyme or increasing/decreasing the amount of substrate for the enzyme in the cell, etc. The portion of the specification referred to by applicants indicates that the level of activity of the **enzyme molecule** is not altered in any way but only that the amount of the substrate of the enzyme is changed by virtue of expression of GnTIII. While it is true that the level of core α-1,6-fucosyltransferase enzymatic activity in the cell is reduced by virtue of the decrease in the amount of available substrate for the enzyme, it is again noted that the claims are considerably more broad in scope and the instant specification does not support the broad limitation of **altering the level of activity** of the core α-1,6- fucosyltransferase in the host cell. It is further noted that nowhere in the instant application is core α-1,6-fucosyltransferase specifically recited as an enzyme whose activity is contemplated for alteration. The only portion of the specification which recites core α-1,6-fucosyltransferase involves the expression of GnTIII and the observation that oligosaccharides first modified by GnTIII can no longer be biosynthetic substrates for core α-1,6- fucosyltransferase.

Applicants' arguments and the 37 CFR 1.132 Declaration of Dr. Umana, filed 8/21/06 addressing the 35 USC 112,1st paragraph (enablement and written description) rejections are persuasive.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 86-88, 90-91, 97-98, 102-103, 106-107, 110-113, 120-121, 123, 125, 129, 131-132, 159-160 and 163-165 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-27 of copending Application No. 11/199,232 (hereafter the '232 application). Although the conflicting claims are not identical, they are not patentably distinct from each other because of reasons of record in the previous Office Action (mailed 4/11/06).

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Applicants request that this provisional rejection be held in abeyance until otherwise allowable claims are identified.

In response, the examiner notes that the rejection will be maintained. Newly added claims 163-165 are added to the rejection as a result of applicants' amendment filed 8/21/06. The subject matter of the new claims is not patentably distinct form the subject matter of claims 1-27 of the '232 application because both sets of claims encompass a entire IgG Fc region (or portion thereof) which would naturally contain a CH2 domain.

Claims 86-88, 90-91, 97-98, 102-103, 106-107, 110-113, 120-121, 123, 125, 129, 131-132, 159-160 and 163-165 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-10 of U.S. Patent No. 6,602,684 (hereafter the '684 patent). Although the conflicting claims are not identical, they are not patentably distinct from each other because of reasons of record in the previous Office Action. Newly added claims 163-165 are included because both sets of claims recite generation of antibodies which would contain an entire IgG Fc region or fragment thereof. The IgG antibody Fc regions are recited as specific embodiments in the '684 patent and hence would have been obvious to the ordinary skilled artisan.

Applicants have submitted a Terminal Disclaimer on 1/22/07. The Terminal disclaimer is not acceptable because it is not signed by an attorney of record and does not include a statement (certificate) under 37 CFR 3.73B. The rejection will be maintained until a suitable Terminal Disclaimer is received.

Any rejections not repeated in this Office Action are withdrawn.

No Claims are allowed.

Claims 89, 92-96, 99-101, 104-105, 108-109, 114-119, 122, 126-128, 130 and 158 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Guzo, Ph.D., whose telephone number is (571) 272-0767. The examiner can normally be reached on Monday-Thursday from 8:00 AM to 5:30 PM. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Woitach, can be reached on (571) 272-0739. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

DAVID GUZO
PRIMARY EXAMINER

David Guzo
September 1, 2007